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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,523	10/07/2003	Ahmed F. Ghouri	MYOWN.001A	5056

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EXAMINER	
LE, LINH GIANG	

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
04/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/680,523	GHOURI, AHMED F.	
	Examiner	Art Unit	
	MICHELLE LE	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to application filed 07 October 2003. It is noted that application claims benefit of provisional application 60/488,360 filed 17 July 2003. Claims 1-48 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-5, 22-25, 30-38, and 39-41 are directed to non-statutory subject matter. Claims 1-5, 22-25, 30-38, and 39-41 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions, a 35 U.S.C § 101 process must (1) be tied to a particular machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876).

There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent- eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable

process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such a data gathering or outputting, is not sufficient to pass the test.

Here, applicant's method steps are not tied to a particular machine and do not perform a transformation. Independent claims 1, 22, 30 and 39 are directed towards a method for the cost-effective use of medications. The claims are not tied to any particular apparatus for which to determine the cost-effective use of medications, thus recites purely mental steps. The method further does not identify any material that is being changed to a different state. Therefore, claims 1, 22, 30 and 39 are not directed toward a patent eligible process under 35 USC 101.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1-5, 22-25, 30-38, and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. In the method claims Applicant fails to recite any structure or machine for performing the method

steps. The claims are thus indefinite for failing to distinctly claim the subject matter of the invention.

7. Claims 1, 6, 12, 30, 39, 42 recite the limitation "the patient cost." Claims 1, 6 and 42 recite "the cost-effectiveness." Claims 22 and 26 recite the limitation "the patient." Claim 26 recites the limitation "the efficiency." Claim 39 recites the limitation "the probability of efficacy." There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (2004/0039602) in view of Bodsworth (2002/0095314).

10. As per claim 1, Greenberg and Bodsworth collectively teach a method for the cost-effective use of medications, comprising:

adjusting the patient cost for at least one medication treatment therapy according to the cost-effectiveness of the medication treatment therapy (Greenberg; para. 32; Bodsworth; paras. 23, 24, 52); and

providing a physician with the adjusted patient cost of the medication treatment therapy (Bodsworth 61-63).

It would have been obvious to combine the teachings of Bodsworth and Greenberg with the motivation of decreasing the "knowledge deficit" in prescribing medicine (Bodsworth; Para. 7).

11. As per claim 2, Bodsworth teaches wherein adjusting the patient cost is based at least in part on patient medication treatment therapy history (Bodsworth; paras. 16 and 17).

12. As per claim 3, Greenberg teaches wherein adjusting the patient cost is based on at least one patient attribute (Greenberg; paras. 31 and 32).

13. As per claim 4, Greenberg teaches wherein the patient attribute includes at least one of: age, sex, weight, past and current medications, co-existing diseases, surgical history, allergies, laboratory findings, and social history (Greenberg; para. 21).

14. As per claim 5, Bodsworth teaches wherein the cost-effectiveness of the medication treatment therapy is based on the overall cost of treatment, including treatment of side-effects related to medication therapy (Bodsworth 61-63).

15. As per claim 6, Bodsworth and Greenberg teach a system for the cost-effective use of medications, comprising:

a user interface, configured to receive input from a user and display information (Greenberg; para. 23);

a cost-effectiveness analysis means, configured to determine the cost- effectiveness of a plurality of medication treatment therapies (Bodsworth; para. 61-63); and

a patient cost adjustment means, configured to adjust the patient cost for each of the medication treatment therapies according to cost-effectiveness data from the cost-effectiveness analysis means, wherein the adjusted patient cost for each medication treatment therapy is displayed on the user interface (Bodsworth; para. 61-63).

It would have been obvious to combine the teachings of Bodsworth and Greenberg with the motivation of decreasing the “knowledge deficit” in prescribing medicine (Bodsworth; Para. 7).

16. As per claim 7, Greenberg teaches wherein the cost-effectiveness of a medication treatment therapy is based at least in part on at least one patient attribute (Greenberg; paras. 31 and 32).

17. As per claim 8, Greenberg teaches wherein the patient attribute includes at least one of:

age, sex, weight, past medications, current medications, co-existing diseases, surgical history, allergies, laboratory findings, and social history (Greenberg; para. 21).

18. As per claim 9, Bodsworth teaches wherein the cost-effectiveness of a medication treatment therapy is based at least in part on the risk of complications for the medication treatment therapy (Bodsworth; paras. 61-63).

19. As per claim 10, Greenberg teaches wherein the plurality of medication treatment therapies are determined based on information provided at the user interface Greenberg; paras. 27 and 28).

20. As per claim 11, Greenberg teaches wherein the information provided at the user interface includes at least one of patient symptoms, diagnosis, and type of medication treatment therapy, whether by drug class, indication, or chemical structure (Greenberg; para. 23).

21. Claims 12-21; 22-25; 26-29; 30-38; 39-41; and 42-48 repeat substantially the same limitations as claims 1-11 and thus the claims are also rejected over Greenberg in view of Bodsworth under 35 USC 103(a). The reasons for rejection from above are incorporated herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE LE whose telephone number is (571)272-8207. The examiner can normally be reached on 8 AM - 5PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gerald O'Connor can be reached on 571-272-3600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/27/09
/Michelle Linh-Giang Le/
Examiner, Art Unit 3686

/Robert Morgan/
Primary Examiner, Art Unit 3626